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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/737,258	12/15/2003	Manabu Ishikawa	P/3541-53	5787

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EXAMINER	
ALIKHANI, SHADI	

ART UNIT	PAPER NUMBER
3734	

MAIL DATE	DELIVERY MODE
10/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/737,258	ISHIKAWA, MANABU	
	Examiner	Art Unit	
	SHADI ALIKHANI	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date ___.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. This action is in reply to the application filed on 12/15/2003 and the amendment filed on 07/02/2008.

2. Claims 1-55 have been amended.

3. Claims 1-55 are currently pending and have been examined.

Response to Arguments

4. Applicant's arguments filed on 07/02/2008 have been fully considered but they are not persuasive. The Applicant argues that Farrell does not teach a hole puncturing probe. Farrell however, in at least column 1, lines 42-47 disclose creating a small perforation or "puncture hole" using a needle and dilating the hole gradually without the risk of tearing the tissue. Furthermore, the Examiner notes that the Applicant's amendment of "a tip end configured for forming a puncture hole in [[a]] living tissue" is considered functional language and merely means that the device has to be capable of performing the intended use. With regard to the statement of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over "a tip end configured for forming a puncture hole in [[a]] living tissue" which is capable of being used as claimed if one desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

5. Additionally, Applicant's arguments with respect to claims 1-55 have been considered. Based upon the Applicant's amendments and reconsideration of the prior art, the Applicant's arguments are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-4, 9, 14, 27, and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Farrell (US 4,994,027).

Claim 1:

Farrell as shown discloses the following limitations:

- *an elongated probe* (16) *including a first central axis and a tip end configured for forming a puncture hole* (col. 1, ln 40-45) *in a living tissue* (Fig. 1A & 3).
- *a cylindrical sheath (18) including tip and base ends,*
- *a second central axis and a through hole extending along the second central axis between the tip and base ends of the sheath* (Fig. 1C),
- *the sheath being adapted so that the tip end of the probe projects from the tip end of the sheath* (Fig. 2A)*, when the probe is inserted in the through hole of the sheath* (Fig. 3 & 4) *and the first central axis with the second central axis.*
- *a cylindrical dilator* (19) *including tip and base ends,*
- *a third central axis, a through hole extending along the third central axis between the tip and base ends of the dilator, and a puncture hole dilating portion* (14") *configured to dilate the puncture hole formed in the living tissue by the tip end of the probe, at [[in]] the tip end of the dilator* (Fig. 3), *the dilator being adapted so that the tip end of the sheath projects from the tip end of the dilator* (Fig. 2A), *when the sheath is inserted in the through hole of the dilator and the second central axis is aligned with the third central axis.*

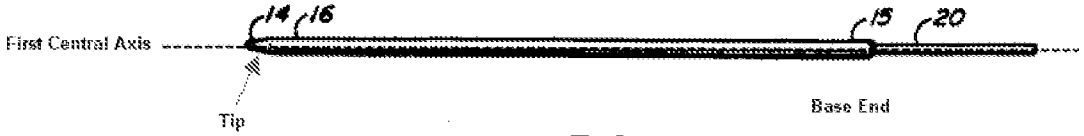

FIG. 1A

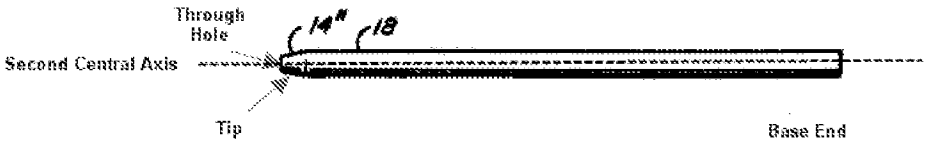

FIG. 1C

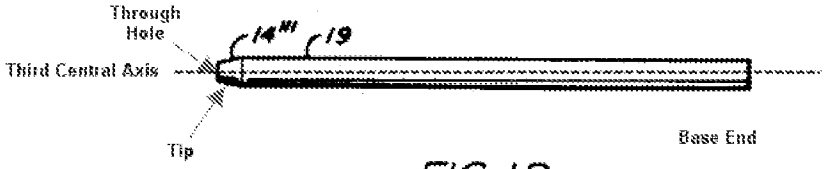

FIG. 1D

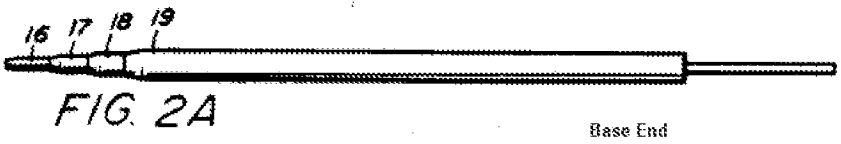

FIG. 2A

- *a cylindrical trocar* (24) *including tip and base ends, a fourth central axis and a through hole extending along the fourth central axis between the tip and base ends of the trocar,*
- *the trocar being adapted so that the tip end of the dilator projects from the tip end of the trocar* (Fig. 3 & 4), *when the dilator is inserted in the through hole of the trocar and the third central axis is aligned with the fourth central axis,*
- *with the probe, sheath and dilator being configured to be removable from the through hole of the trocar and the trocar being retained in a patient's body wall* (col. 3, ln 2-9; col. 3, ln 60-68; col. 4, ln 1-8) *after guiding the trocar between the tip and base ends into the puncture hole formed by the probe.*

- *The trocar system comprising an engaging mechanism* (Fig. 2C & 3; col. 1, ln 48-52; col. 3, ln 2-10; col. 3, ln 60-68) *configured to detachably engage the dilator with the trocar when the dilator is inserted in the trocar and*
- *a user hold portion* (Fig. 3 & 4) *formed by the base ends of the trocar and the dilator being connected and integrated with each other when the trocar is engaged with the dilator by the engaging mechanism* (col. 2, ln 46-52; col. 1, ln 48-52).

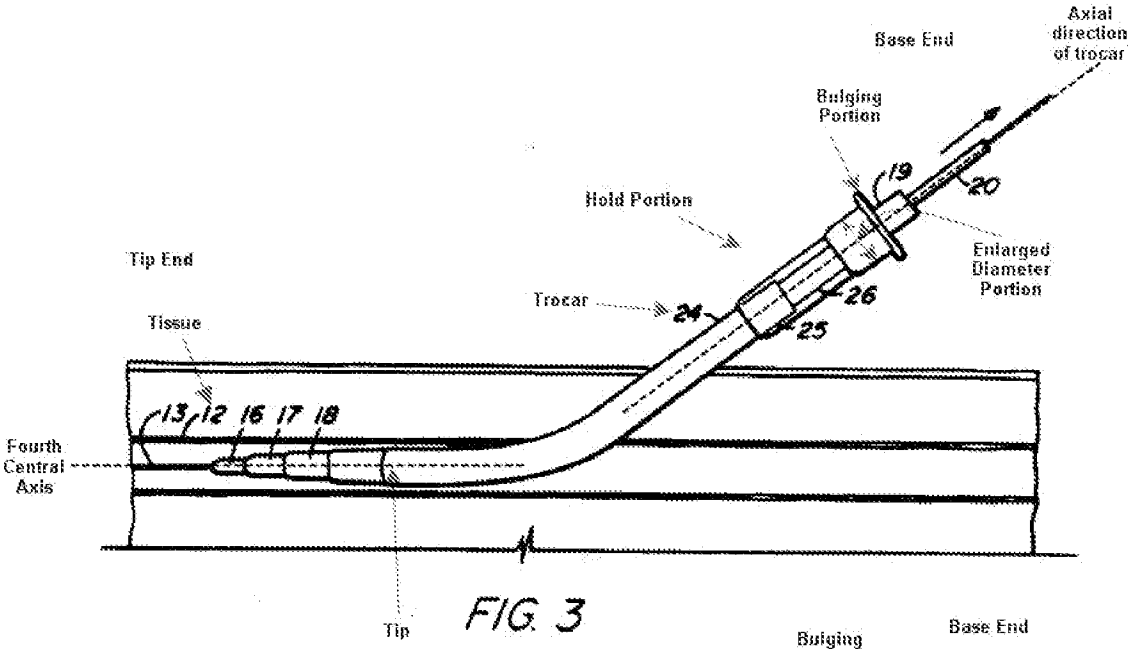

FIG. 3

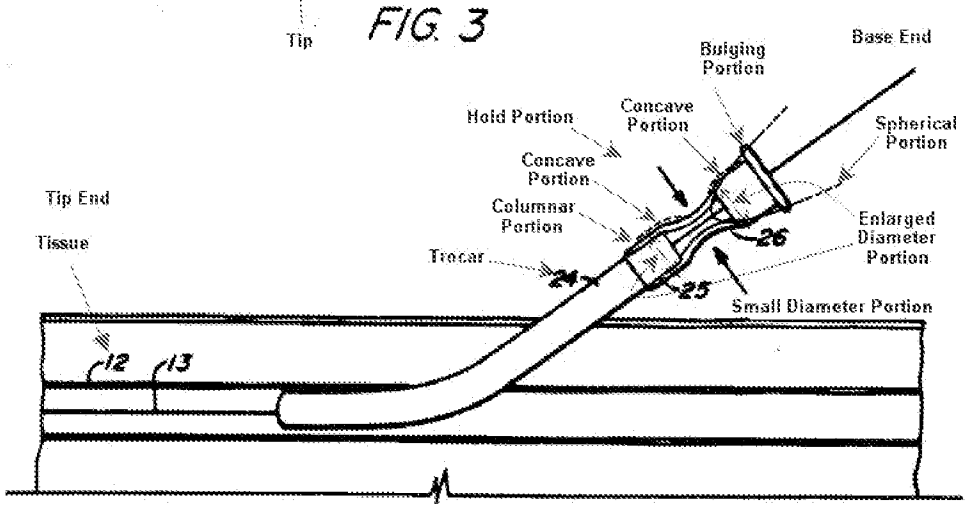

FIG. 4

Claims 2-4, 9, 14, 27, and 29:

Farrell discloses the limitations as shown above and further discloses:

- *the user hold portion* (Fig. 3) *includes:*
- *an enlarged diameter portion, which is disposed on the base end of the dilator having an outer diameter [[is]] enlarged [[with]] relative to the tip end of the dilator* (Fig. 3 & 4)
- *a bulging portion disposed on the base end of the trocar and formed of at least a part of the base end of the trocar extending in a direction along an axial direction of the trocar toward a side opposite the tip end of the trocar* (Fig. 3 & 4).
- *the enlarged diameter portion that includes a concave portion* (Fig. 4) *in which at least a portion of the base end of the trocar on a side opposite the tip end of the trocar is configured to be fitted.*
- *the enlarged diameter portion comprises a small diameter portion* (Fig. 4) *adopted to be held by the operator's finger, and a large diameter portion having a diameter progressively enlarged in a direction toward the tip end of the dilator to a diameter larger than the small diameter portion* (see Fig. 4).
- *the enlarged portion includes a spherical portion to be held by an operator's hand and the spherical portion includes the concave portion* (Fig. 4).
- *the enlarged portion includes a columnar portion to be held by an operator's hand and the columnar portion includes the concave portion* (Fig. 4).
- *the puncturing tip end of the probe has a conical shape* (Fig. 1A) *with a surface of the conical shape being cut away with a planar cut at an acute angle with respect to the axial direction of the probe* (col. 1, ln 37-42).

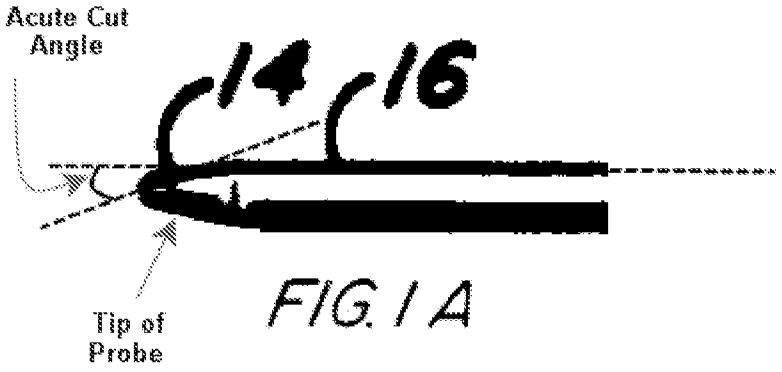

FIG. 1A

- *an elongated probe* (16) *including a first central axis and a tip end for forming a puncture hole in a living tissue* (Fig. 1A & 3).
- *a cylindrical sheath* (18) *including tip and base ends,*
- *a second central axis and a through hole extending along the second central axis between the tip and base ends of the sheath* (Fig. 1C),
- *the sheath being adapted so that the tip end of the probe projects from the tip end of the sheath* (Fig. 2A), *when the probe is inserted in the through hole of the sheath* (Fig. 3 & 4) *align and the first central axis is aligned with the second central axis.*
- *a cylindrical sheath insertion portion* (19) *including tip and base ends,*
- *a third central axis, a through hole extending along the third central axis between the tip and base ends of the sheath insertion portion, and*
- *a puncture hole dilating portion* (14") *to dilate the punctured hole formed in the living tissue by the tip end of the probe in the tip end of the sheath insertion portion* (Fig. 3), *the sheath insertion portion being adapted so that the tip end of the sheath projects from the tip end of the sheath insertion portion* (Fig. 2A), *when the sheath is inserted in the through hole of the sheath insertion portion and the second central axis is aligned with the third central axis* (Fig. 3 & 4).

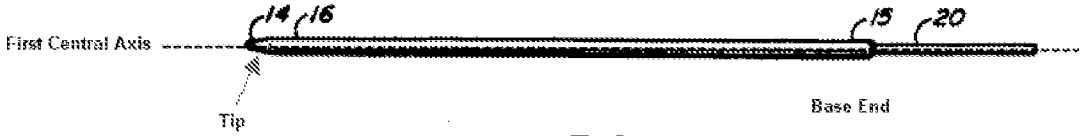

FIG. 1A

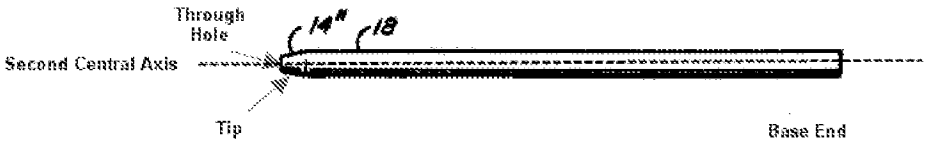

FIG. 1C

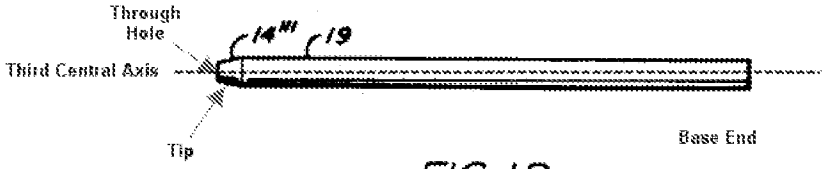

FIG. 1D

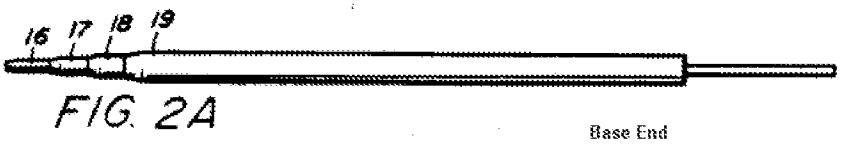

FIG. 2A

- *a cylindrical dilator insertion portion* (24) *which includes tip and base ends,*
- *a fourth central axis and a through hole extending along the fourth central axis between the tip and base ends, the dilator insertion portion being adapted so that the tip end of the sheath insertion portion projects from the tip end of the dilator insertion portion* (Fig. 3 & 4), *when the sheath insertion portion is inserted in the through hole of the dilator insertion portion and the third central axis is aligned with the fourth central axis,*
- *with the probe, sheath and sheath insertion portion configured to be removable from the through hole of the dilator insertion portion to retain the dilator insertion portion in a patient's body wall* (col. 3, ln 2-9; col. 3, ln 60-68; col. 4, ln 1-8) *after guiding the*

dilator insertion portion between the tip and base ends into the punctured hole (Fig. 3 & 4).

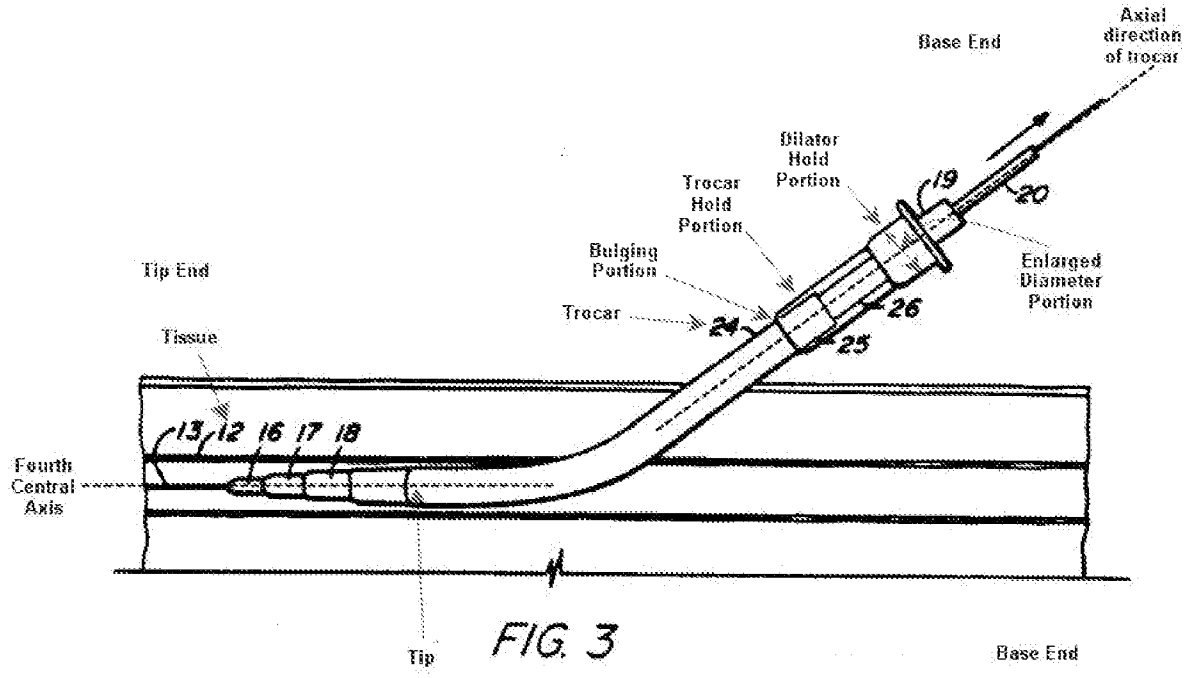

FIG. 3

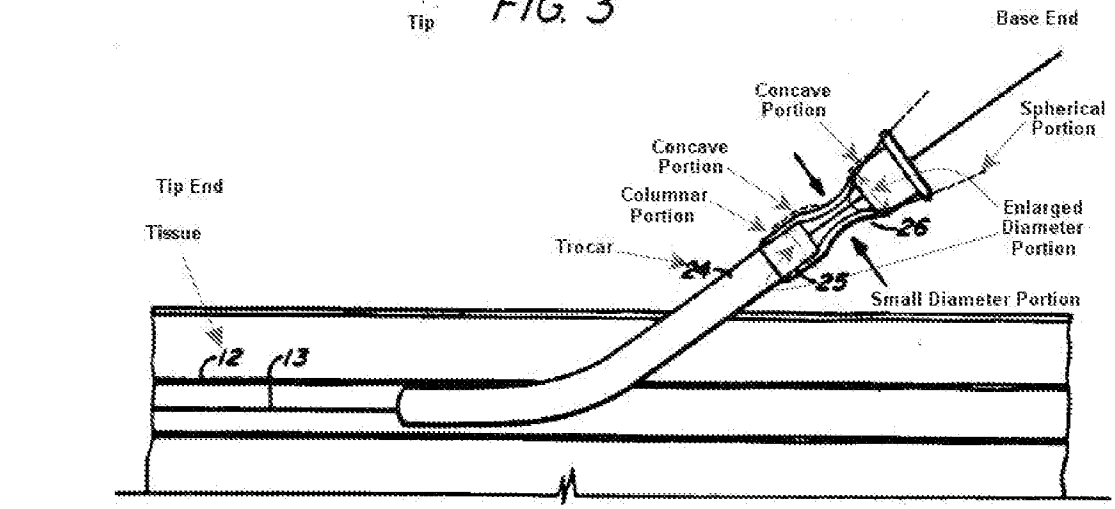

FIG. 4

- *a dilator hold portion* (Fig. 3) *is disposed on the base end of the sheath insertion portion and configured to be held by the operator with the sheath insertion portion is inserted in the dilator insertion portion and having an outer diameter enlarged relative to the tip end of the sheath insertion portion* (Fig. 3).

- *a trocar hold portion* (Fig. 3), *is disposed on the base end of the dilator insertion portion and configured to be held by the operator with the sheath insertion portion [[is]] inserted in the dilator insertion portion,*
- *the trocar hold portion having a portion toward the tip end of the dilator insertion portion which bulges* (Fig. 4) *in a direction away from the axis of the dilator insertion portion, and a portion on at least a side opposite the tip end of the dilator insertion portion [[is]] being held by the dilator hold portion when the sheath insertion portion is inserted in the dilator insertion portion.*

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 5-7, 10-12, 15-17, 19-21, 24-25, 30-34, 37-39, 41-44, 46-48, 51-52, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farrell (US 4,994,027) in view of Maaskamp et al (US 6,013,046) or Maaskamp herein.

Claim 5:

Farrell discloses the limitations as shown above and further discloses *the bulging portion* (Fig. 3 & 4). Farrell does not explicitly disclose that the bulging portion *has a conical shape having a small diameter toward the tip end of the trocar and whose diameter is enlarged away from the tip end of the trocar*. However, Maaskamp discloses a bulging portion (24) on a sleeve-shielded needle device that has a conical shape (Fig. 2) having a small diameter toward the tip end of the trocar and whose diameter is enlarged away from the tip end of the trocar (col 2, ln 64-67).

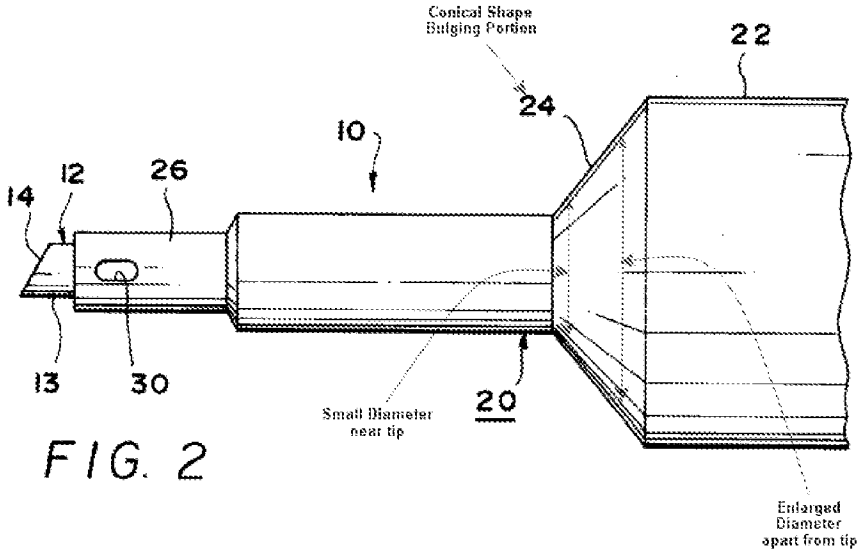

FIG. 2

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell and Maaskamp before him or her to modify the multi-sleeve trocar device of Farrell to include the conical shape bulging portion of Maaskamp. The motivation for doing so would have been to provide a transition component from the trocar to the multi-sleeve dilator device in order to improve holding or maneuvering the device into and out of the body and also facilitate holding of the device during the separation of the trocar and the different sleeves from one another.

Claim 6:

Farrell discloses the limitations as shown above and further discloses *the probe* (16). Farrell does not appear to explicitly disclose that the probe *includes an ultrasonic transducer provided on [[the]] a base of the probe, the ultrasonic transducer being configured to be capable of transmitting an ultrasonic vibration and to be capable of oscillating the ultrasonic vibration toward the puncturing tip end of the probe*. However, Maaskamp discloses an ultrasonic surgical device (10) having an ultrasonic needle tip (13) with a cutting edge (14) and an encompassing sleeve combination (Fig. 2) that is formed on the base end of the probe so as to be capable of transmitting an ultrasonic vibration toward the tip end of the probe (col. 1, ln 18-20; col. 1, ln 22-24; col. 2, ln 29-33).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell and Maaskamp before him or her to modify the multi-sleeve trocar device of Farrell to include a probe with an ultrasonic transducer on the base end. The motivation for doing so would have been to provide a more efficient ultrasonic vibration of the needle tip in order to cut or penetrate the tissue of interest more precisely and accurately.

Claim 7:

Farrell discloses the limitations as shown above and further discloses *the puncturing tip end of the probe has a conical shape* (Fig. 1A) *with a surface cut away with a planar cut at an acute cut angle with respect to the axial direction of the probe* (col. 1, ln 37-42).

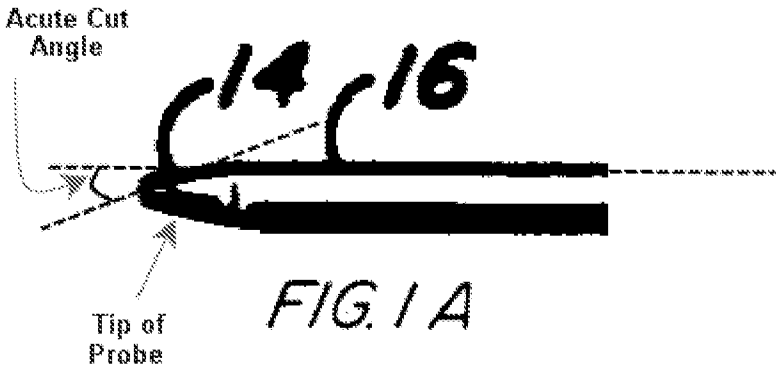

FIG. 1A

Claim 10:

Farrell discloses the limitations as shown above and further discloses *the bulging portion* (Fig. 3 & 4). Farrell does not explicitly disclose that the bulging portion *has a conical shape having a small diameter toward the tip end of the trocar and whose diameter is enlarged away from the tip end of the trocar*. However, Maaskamp discloses a bulging portion (24) on a sleeve-shielded needle device that has a conical shape (Fig. 2) having a small diameter toward the tip end of the trocar and whose diameter is enlarged away from the tip end of the trocar (col 2, ln 64-67).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell and Maaskamp before him or her to modify the multi-sleeve trocar device of Farrell to include the conical shape bulging portion of Maaskamp. The motivation for doing so would have been to provide a transition component from the trocar to the multi-sleeve dilator device in order to improve holding or maneuvering the device into and out of the body and also facilitate holding of the device during the separation of the trocar and the different sleeves from one another.

Claim 11:

Farrell discloses the limitations as shown above and further discloses *the probe* (16). Farrell does not appear to explicitly disclose that the probe *includes an ultrasonic transducer provided on [[the]] a base of the probe, to be capable of transmitting an ultrasonic vibration and to be capable of oscillating the ultrasonic vibration toward the tip end of the probe*. However, Maaskamp discloses an ultrasonic surgical device (10) having an ultrasonic needle tip (13) with a cutting edge (14) and an encompassing sleeve combination (Fig. 2) that is formed on the base end of the probe so as to be capable of transmitting an ultrasonic vibration toward the tip end of the probe (col. 1, ln 18-20; col. 1, ln 22-24; col. 2, ln 29-33).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell and Maaskamp before him or her to modify the multi-sleeve trocar device of Farrell to include a probe with an ultrasonic transducer on the base end. The

motivation for doing so would have been to provide a more efficient ultrasonic vibration of the needle tip in order to cut or penetrate the tissue of interest more precisely and accurately.

Claim 12:

Farrell discloses the limitations as shown above and further discloses *the puncturing tip end of the probe has a conical shape* (Fig. 1A) *with a surface cut away with a planar cut at an acute cut angle with respect to the axial direction of the probe* (col. 1, ln 37-42).

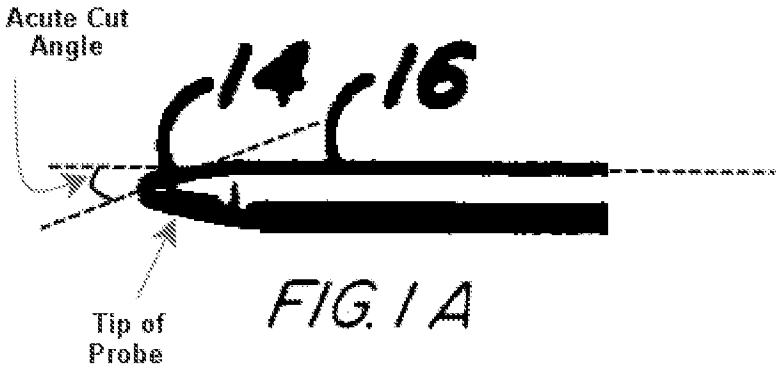

FIG. 1A

Claim 15:

Farrell discloses the limitations as shown above and further discloses *the bulging portion* (Fig. 3 & 4). Farrell does not explicitly disclose that the bulging portion *has a conical shape having a small diameter toward the tip end of the trocar and whose diameter is enlarged away from the tip end of the trocar*. However, Maaskamp discloses a bulging portion (24) on a sleeve-shielded needle device that has a conical shape (Fig. 2) having a small diameter toward the tip end of the trocar and whose diameter is enlarged away from the tip end of the trocar (col 2, ln 64-67).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell and Maaskamp before him or her to modify the multi-sleeve trocar device of Farrell to include the conical shape bulging portion of Maaskamp. The motivation for doing so would have been to provide a transition component from the trocar to the multi-

sleeve dilator device in order to improve holding or maneuvering the device into and out of the body and also facilitate holding of the device during the separation of the trocar and the different sleeves from one another.

Claim 16:

Farrell discloses the limitations as shown above and further discloses *the probe* (16). Farrell does not appear to explicitly disclose that the probe *includes an ultrasonic transducer provided on [[the]] a base of the probe, the ultrasonic transducer being configured to be capable of transmitting an ultrasonic vibration and to be capable of oscillating the ultrasonic vibration toward the tip end of the probe*. However, Maaskamp discloses an ultrasonic surgical device (10) having an ultrasonic needle tip (13) with a cutting edge (14) and an encompassing sleeve combination (Fig. 2) that is formed on the base end of the probe so as to be capable of transmitting an ultrasonic vibration toward the tip end of the probe (col. 1, ln 18-20; col. 1, ln 22-24; col. 2, ln 29-33).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell and Maaskamp before him or her to modify the multi-sleeve trocar device of Farrell to include a probe with an ultrasonic transducer on the base end. The motivation for doing so would have been to provide a more efficient ultrasonic vibration of the needle tip in order to cut or penetrate the tissue of interest more precisely and accurately.

Claim 17:

Farrell discloses the limitations as shown above and further discloses *the puncturing tip end of the probe has a conical shape* (Fig. 1A) *with a surface cut away with a planar cut at an acute cut angle with respect to the axial direction of the probe* (col. 1, ln 37-42).

Claim 19:

Farrell discloses the limitations as shown above and further discloses *the bulging portion* (Fig. 3 & 4). Farrell does not explicitly disclose that the bulging portion *has a conical shape having a small diameter toward the tip end of the trocar and whose diameter is enlarged away from the tip end of the trocar*. However, Maaskamp discloses a bulging portion (24) on a sleeve-shielded needle device that has a conical shape (Fig. 2) having a small diameter toward the tip end of the trocar and whose diameter is enlarged away from the tip end of the trocar (col 2, ln 64-67).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell and Maaskamp before him or her to modify the multi-sleeve trocar device of Farrell to include the conical shape bulging portion of Maaskamp. The motivation for doing so would have been to provide a transition component from the trocar to the multi-sleeve dilator device in order to improve holding or maneuvering the device into and out of the body and also facilitate holding of the device during the separation of the trocar and the different sleeves from one another.

Claims 20 and 24:

Farrell discloses the limitations as shown above and further discloses *the probe* (16). Farrell does not appear to explicitly disclose that the probe *includes an ultrasonic transducer provided on [[the]] a base of the probe, the ultrasonic transducer being configured to be capable of transmitting an ultrasonic vibration and to be capable of oscillating the ultrasonic vibration toward the tip end of the probe*. However, Maaskamp discloses an ultrasonic surgical device (10) having an ultrasonic needle tip (13) with a cutting edge (14) and an encompassing sleeve combination (Fig. 2) that is formed on the base end of the probe so as to be capable of transmitting an ultrasonic vibration toward the tip end of the probe (col. 1, ln 18-20; col. 1, ln 22-24; col. 2, ln 29-33).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell and Maaskamp before him or her to modify the multi-sleeve

trocar device of Farrell to include a probe with an ultrasonic transducer on the base end. The motivation for doing so would have been to provide a more efficient ultrasonic vibration of the needle tip in order to cut or penetrate the tissue of interest more precisely and accurately.

Claim 21:

Farrell discloses the limitations as shown above and further discloses *the puncturing tip end of the probe has a conical shape* (Fig. 1A) *with a surface cut away with a planar cut at an acute cut angle with respect to the axial direction of the probe* (col. 1, ln 37-42).

Claim 25:

Farrell discloses the limitations as shown above and further discloses *the puncturing tip end of the probe has a conical shape* (Fig. 1A) *with a surface of the conical shape being cut away with a planar cut at an acute cut angle with respect to the axial direction of the probe* (col. 1, ln 37-42).

Claim 30:

Farrell discloses the limitations as shown above and further discloses *the dilator hold portion includes an enlarged diameter portion* (Fig. 3) *whose diameter is enlarged relative to the tip end of the sheath insertion portion and a trocar hold portion* (Fig. 3) *includes a bulging portion*. Farrell does not appear to explicitly disclose that *the bulging portion extends in a direction extending along from the axial direction of the dilator insertion portion* (Fig. 3 & 4) *toward a side of the trocar hold portion opposite the tip end of the dilator insertion portion at least a part of the trocar held portion is covered with the dilator hold portion when the sheath insertion portion is inserted in the dilator insertion portion*. However, Maaskamp discloses a bulging portion (24) on a sleeve-shielded needle device that has a conical shape (Fig. 2) having a small diameter on the side in the vicinity of the tip end of the dilator insertion portion and whose diameter is enlarged apart from the tip end of the dilator insertion portion (col 2, ln 64-67).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell and Maaskamp before him or her to modify the multi-sleeve trocar device of Farrell to include the conical shape bulging portion of Maaskamp. The motivation for doing so would have been to provide a bulging conical transition component from the trocar to the multi-sleeve dilator device in order to improve holding or maneuvering the device into and out of the body and also facilitate holding of the device during the separation of the trocar and the different sleeves from one another.

Claim 31:

Farrell discloses the limitations as shown above and further discloses *the englarged diameter portion includes a small diameter portion to be held by the operator's finger, and a large diameter portion whose diameter is progressively enlarged toward the tip end of the sheath insertion portion to a diameter larger than the small diameter portion* (Fig. 4).

Claim 32:

Farrell discloses the limitations as shown above and further discloses *a bulging portion* (Fig. 3 & 4). Farrell does not explicitly disclose that *the bulging portion has a conical shape having a small diameter toward the tip end of the dilator insertion portion and whose diameter is enlarged away from the tip end of the dilator insertion portion*, but Maaskamp as shown discloses a bulging portion (24) on a sleeve-shielded needle device that has a conical shape (Fig. 2) having a small diameter toward the tip end of the dilator insertion portion and whose diameter is enlarged away from the tip end of the dilator insertion portion (col 2, ln 64-67).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell and Maaskamp before him or her to modify the multi-sleeve trocar device of Farrell to include the conical shape bulging portion of Maaskamp. The motivation for doing so would have been to provide a bulging conical transition component from the trocar to the multi-sleeve dilator device in order to improve holding or maneuvering the device into and out

of the body and also facilitate holding of the device during the separation of the trocar and the different sleeves from one another.

Claim 33:

Farrell discloses the limitations as shown above and further discloses *the probe* (16). Farrell does not appear to explicitly disclose that the probe *includes an ultrasonic transducer provided on [[the]] a base of the probe, the ultrasonic transducer being configured to be capable of transmitting an ultrasonic vibration and to be capable of oscillating the ultrasonic vibration toward the tip end of the probe*. However, Maaskamp discloses an ultrasonic surgical device (10) having an ultrasonic needle tip (13) with a cutting edge (14) and an encompassing sleeve combination (Fig. 2) that is formed on the base end of the probe so as to be capable of transmitting an ultrasonic vibration toward the tip end of the probe (col. 1, ln 18-20; col. 1, ln 22-24; col. 2, ln 29-33).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell and Maaskamp before him or her to modify the multi-sleeve trocar device of Farrell to include a probe with an ultrasonic transducer on the base end. The motivation for doing so would have been to provide a more efficient ultrasonic vibration of the needle tip in order to cut or penetrate the tissue of interest more precisely and accurately.

Claim 34:

Farrell discloses the limitations as shown above and further discloses *the puncturing tip end of the probe has a conical shape* (Fig. 1A) *with a surface of the conical shape being cut away at an acute cut angle with respect to the axial direction of the probe* (col. 1, ln 37-42).

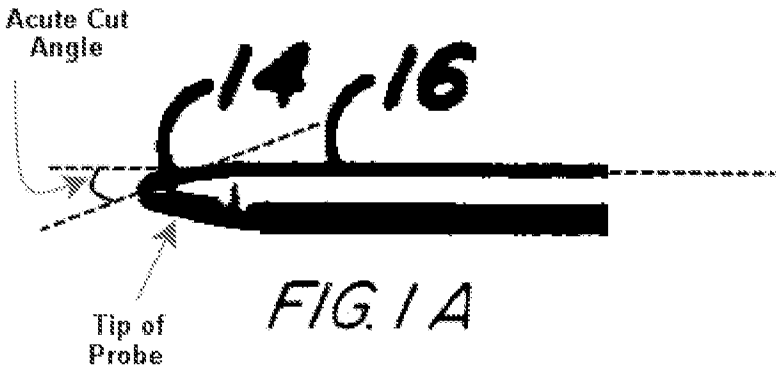

FIG. 1A

Claim 36:

Farrell discloses the limitations as shown above and further discloses *the enlarged diameter portion includes a spherical portion to be held by an operator's hand and the spherical portion includes the concave portion* (Fig. 3 & 4).

Claim 37:

Farrell discloses the limitations as shown above and further discloses *a bulging portion* (Fig. 3 & 4). Farrell does not explicitly disclose that *the bulging portion has a conical shape having a small diameter toward the tip end of the dilator insertion portion and whose diameter is enlarged away from the tip end of the dilator insertion portion*, but Maaskamp as shown discloses a bulging portion (24) on a sleeve-shielded needle device that has a conical shape (Fig. 2) having a small diameter toward the tip end of the dilator insertion portion and whose diameter is enlarged away from the tip end of the dilator insertion portion (col 2, ln 64-67).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell and Maaskamp before him or her to modify the multi-sleeve trocar device of Farrell to include the conical shape bulging portion of Maaskamp. The motivation for doing so would have been to provide a bulging conical transition component from the trocar to the multi-sleeve dilator device in order to improve holding or maneuvering the device into and out of the body and also facilitate holding of the device during the separation of the trocar and the different sleeves from one another.

Claim 38:

Farrell discloses the limitations as shown above and further discloses *the probe* (16). Farrell does not appear to explicitly disclose that the probe *includes an ultrasonic transducer provided on [[the]] a base of the probe, the ultrasonic transducer being configured to be capable of transmitting an ultrasonic vibration and to be capable of oscillating the ultrasonic vibration toward the tip end of the probe.* However, Maaskamp discloses an ultrasonic surgical device (10) having an ultrasonic needle tip (13) with a cutting edge (14) and an encompassing sleeve combination (Fig. 2) that is formed on the base end of the probe so as to be capable of transmitting an ultrasonic vibration toward the tip end of the probe (col. 1, ln 18-20; col. 1, ln 22-24; col. 2, ln 29-33).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell and Maaskamp before him or her to modify the multi-sleeve trocar device of Farrell to include a probe with an ultrasonic transducer on the base end. The motivation for doing so would have been to provide a more efficient ultrasonic vibration of the needle tip in order to cut or penetrate the tissue of interest more precisely and accurately.

Claim 34:

Farrell discloses the limitations as shown above and further discloses *the puncturing tip end of the probe has a conical shape* (Fig. 1A) *with a surface of the conical shape being cut away at an acute cut angle with respect to the axial direction of the probe* (col. 1, ln 37-42).

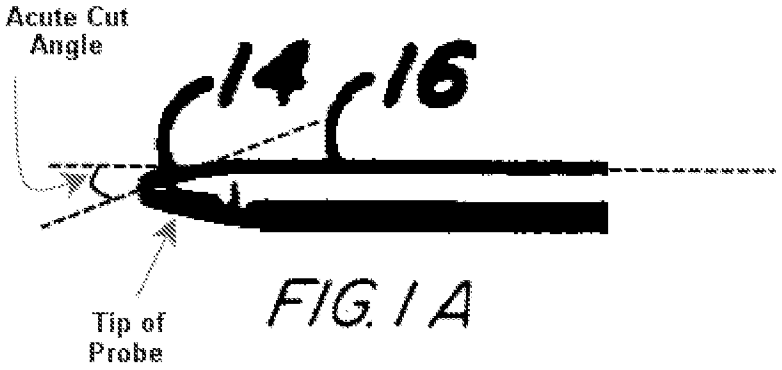

FIG. 1A

Claim 41:

Farrell discloses the limitations as shown above and further discloses *the enlarged diameter portion includes a spherical portion to be held by an operator's hand and the spherical portion includes the concave portion* (Fig. 3 & 4).

Claim 42:

Farrell discloses the limitations as shown above and further discloses *a bulging portion* (Fig. 3 & 4). Farrell does not explicitly disclose that *the bulging portion has a conical shape having a small diameter toward the tip end of the dilator insertion portion and whose diameter is enlarged away from the tip end of the dilator insertion portion*, but Maaskamp as shown discloses a bulging portion (24) on a sleeve-shielded needle device that has a conical shape (Fig. 2) having a small diameter toward the tip end of the dilator insertion portion and whose diameter is enlarged away from the tip end of the dilator insertion portion (col 2, ln 64-67).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell and Maaskamp before him or her to modify the multi-sleeve trocar device of Farrell to include the conical shape bulging portion of Maaskamp. The motivation for doing so would have been to provide a bulging conical transition component from the trocar to the multi-sleeve dilator device in order to improve holding or maneuvering the device into and out of the body and also facilitate holding of the device during the separation of the trocar and the different sleeves from one another.

Claim 43:

Farrell discloses the limitations as shown above and further discloses *the probe* (16). Farrell does not appear to explicitly disclose that the probe *includes an ultrasonic transducer provided on [[the]] a base of the probe, the ultrasonic transducer being configured to be capable of transmitting an ultrasonic vibration and to be capable of oscillating the ultrasonic vibration toward the tip end of the probe*. However, Maaskamp discloses an ultrasonic surgical device (10)

having an ultrasonic needle tip (13) with a cutting edge (14) and an encompassing sleeve combination (Fig. 2) that is formed on the base end of the probe so as to be capable of transmitting an ultrasonic vibration toward the tip end of the probe (col. 1, ln 18-20; col. 1, ln 22-24; col. 2, ln 29-33).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell and Maaskamp before him or her to modify the multi-sleeve trocar device of Farrell to include a probe with an ultrasonic transducer on the base end. The motivation for doing so would have been to provide a more efficient ultrasonic vibration of the needle tip in order to cut or penetrate the tissue of interest more precisely and accurately.

Claim 44:

Farrell discloses the limitations as shown above and further discloses *the puncturing tip end of the probe has a conical shape* (Fig. 1A) *with a surface cut away with a planar cut at an acute cut angle with respect to the axial direction of the probe* (col. 1, ln 37-42).

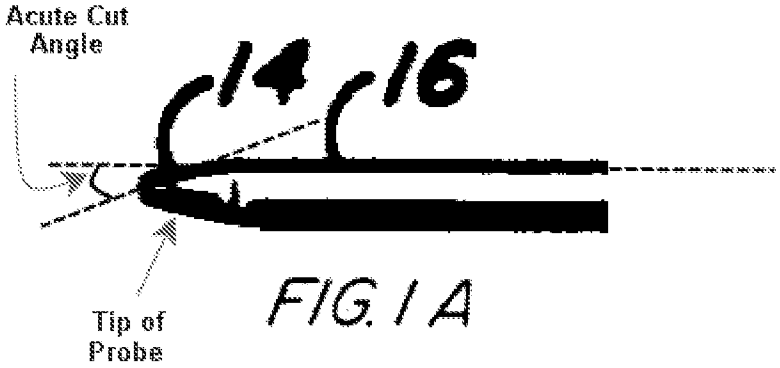

FIG. 1A

Claim 46:

Farrell discloses the limitations as shown above and further discloses *the enlarged diameter portion includes a spherical portion to be held by an operator's hand and the spherical portion includes the concave portion* (Fig. 3 & 4).

Claim 47:

Farrell discloses the limitations as shown above and further discloses *the probe* (16). Farrell does not appear to explicitly disclose that the probe *includes an ultrasonic transducer provided on [[the]] a base of the probe, the ultrasonic transducer being configured to be capable of transmitting an ultrasonic vibration and to be capable of oscillating the ultrasonic vibration toward the tip end of the probe.* However, Maaskamp discloses an ultrasonic surgical device (10) having an ultrasonic needle tip (13) with a cutting edge (14) and an encompassing sleeve combination (Fig. 2) that is formed on the base end of the probe so as to be capable of transmitting an ultrasonic vibration toward the tip end of the probe (col. 1, ln 18-20; col. 1, ln 22-24; col. 2, ln 29-33).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell and Maaskamp before him or her to modify the multi-sleeve trocar device of Farrell to include a probe with an ultrasonic transducer on the base end. The motivation for doing so would have been to provide a more efficient ultrasonic vibration of the needle tip in order to cut or penetrate the tissue of interest more precisely and accurately.

Claim 48:

Farrell discloses the limitations as shown above and further discloses *the puncturing tip end of the probe has a conical shape* (Fig. 1A) *with a surface cut away with a planar cut at an acute cut angle with respect to the axial direction of the probe* (col. 1, ln 37-42).

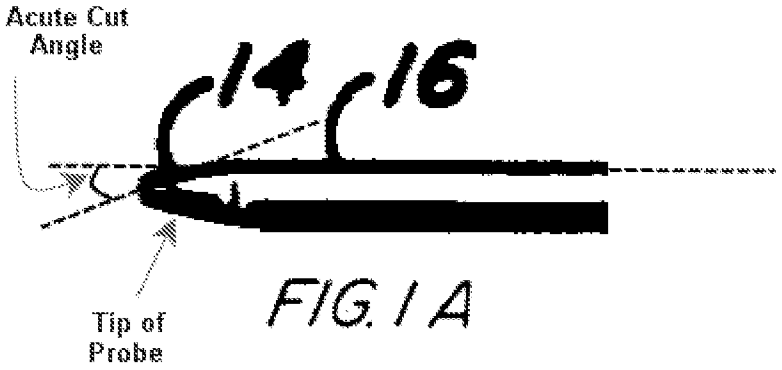

FIG. 1A

Claim 51:

Farrell discloses the limitations as shown above and further discloses *the probe* (16). Farrell does not appear to explicitly disclose that the probe *includes an ultrasonic transducer provided on [[the]] a base of the probe, the ultrasonic transducer being configured to be capable of transmitting an ultrasonic vibration and to be capable of oscillating the ultrasonic vibration toward the tip end of the probe.* However, Maaskamp discloses an ultrasonic surgical device (10) having an ultrasonic needle tip (13) with a cutting edge (14) and an encompassing sleeve combination (Fig. 2) that is formed on the base end of the probe so as to be capable of transmitting an ultrasonic vibration toward the tip end of the probe (col. 1, ln 18-20; col. 1, ln 22-24; col. 2, ln 29-33).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell and Maaskamp before him or her to modify the multi-sleeve trocar device of Farrell to include a probe with an ultrasonic transducer on the base end. The motivation for doing so would have been to provide a more efficient ultrasonic vibration of the needle tip in order to cut or penetrate the tissue of interest more precisely and accurately.

Claim 52 and 54:

Farrell discloses the limitations as shown above and further discloses *the puncturing tip end of the probe has a conical shape* (Fig. 1A) *with a surface cut away with a planar cut at an acute cut angle with respect to the axial direction of the probe* (col. 1, ln 37-42).

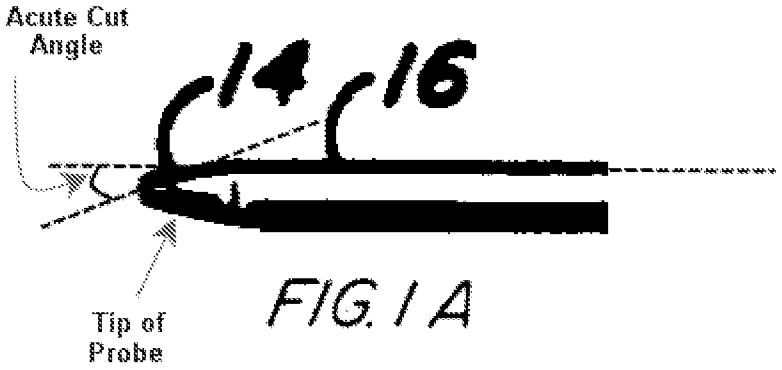

FIG. 1A

6. Claims 8, 13, 18, 22, 26, 28, 35, 40, 45, 49, 53, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farrell (US 4,994,027) in view of Maaskamp et al (US 6,013,046) or Maaskamp herein, further in view of Kambin (US 4,573,448).

Claim 8, 13, 18, 22, 26, 28, 35, 40, 45, 49, 53, and 55:

The combination of Farrell and Maaskamp disclose an acute cut angle with respect to the axial direction of the probe (Fig. 1A & Fig. 2). Neither Farrell nor Maaskamp explicitly disclose that *the cut angle is 60 degrees or less with respect to the axial direction of the probe and [[is]] the cut extends over a vertical angle of the tip end of the probe*. However, Kambin discloses a multi-sleeve blunt tip trocar with a beveled needle at about 23 degrees (col. 3, ln 9-11).

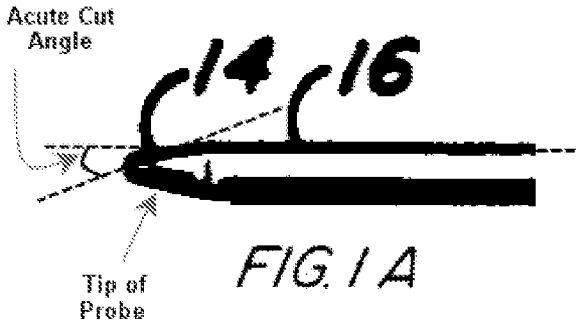

FIG. 1A

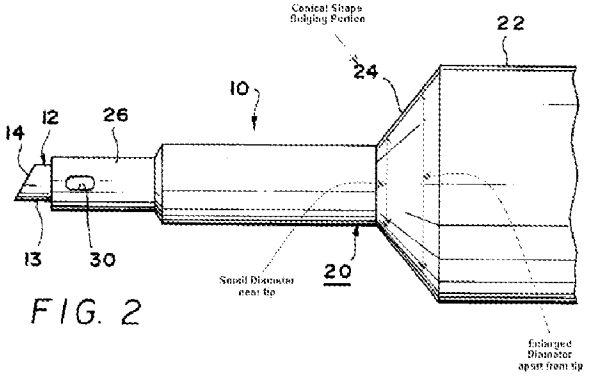

FIG. 2

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell, Maaskamp, and Kambin before him or her to modify the multi-sleeve trocar device of Farrell and Maaskamp to include a cut angle of 60 degrees or less with respect to the axial direction of the probe. The motivation for doing so would be to advance the needle tip in an oblique direction and at the best possible angle in order to penetrate the tissue in the most optimum way.

7. Claims 23 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farrell (US 4,994,027) in view of Kambin (US 4,573,448).

Claim 23 and 50:

Farrell discloses the limitations as shown above and further discloses a hold portion (Fig. 4). Farrell does not explicitly disclose that *the hold portion includes at least one slip stopping element, which prevents the hold portion from slipping from the operator's hand*. However, Kambin discloses a grip portion (44) or a "hold portion" that includes at least one slip stopper (Fig. 8), which prevents the hold portion from slipping from the operator's hand (col. 3, ln 49-53).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, having the teachings of Farrell and Kambin before him or her to modify the multi-sleeve trocar device of Farrell to include a hold portion with at least one slip stopper. The motivation for doing so would have been to provide a more effective hold portion that can better control handling of the device when being used by the operator.

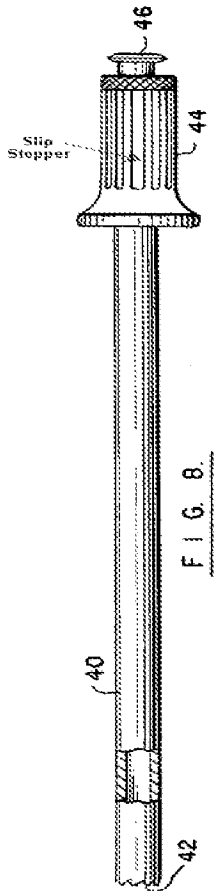

FIG. 8.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHADI ALIKHANI whose telephone number is (571)270-5305. The examiner can normally be reached on Monday - Thursday 10AM - 4PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on 571-272-4996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin T. Truong/ 09/26/2008
Primary Examiner, Art Unit 3734